



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2017-N-1066]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Annual Reporting for Custom Device Exemption

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments (including recommendations) on the collection of information by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to <https://www.reginfo.gov/public/do/PRAMain>. Find this particular information collection by selecting "Currently under Review - Open for Public Comments" or by using the search function. The OMB control number for this information collection is 0910-0767. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Ila S. Mizrachi, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-7726, PRAStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Annual Reporting for Custom Device Exemption

OMB Control Number 0910-0767--Extension

The custom device exemption is set forth at section 520(b)(2)(B) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360j(b)(2)(B)). A custom device is in a narrow category of device that, by virtue of the rarity of the patient's medical condition or physician's special need the device is designed to treat, it would be impractical for the device to comply with premarket review regulations and performance standards.

The Food and Drug Administration Safety and Innovation Act (FDASIA) implemented changes to the custom device exemption contained in section 520(b) of the FD&C Act. The new provision amended the existing custom device exemption and introduced new concepts and procedures for custom devices, such as:

- devices created or modified to comply with the order of an individual physician or dentist;
- the potential for multiple units of a device type (limited to no more than five units per year) qualifying for the custom device exemption; and
- annual reporting requirements by the manufacturer to FDA about devices manufactured and distributed under section 520(b) of the FD&C Act.

Under FDASIA, "devices" that qualify for the custom device exemption contained in section 520(b) of the FD&C Act were clarified to include no more than "five units per year of a particular device type" that otherwise meet all the requirements necessary to qualify for the custom device exemption.

In the *Federal Register* of September 24, 2014 (79 FR 57112), FDA announced the availability of the guidance entitled "Custom Device Exemption." FDA has developed this document to provide guidance to industry and FDA staff about implementation of the custom device exemption contained in the FD&C Act. The intent of the guidance is to define terms used in the custom device exemption, explain how to interpret the "five units per year of a particular device type" language contained in the FD&C Act, describe information that FDA proposes manufacturers should submit in the custom device annual report, and provide recommendations on how to submit an annual report for devices distributed under the custom device exemption.

In the *Federal Register* of February 21, 2020 (85 FR 10175), we published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

FDA estimates the burden of this collection of information as follows:

Table 1.--Estimated Annual Reporting Burden¹

Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Annual reporting for custom devices	34	1	34	40	1,360

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

Our estimated burden for the information collection reflects an overall increase of 40 hours and a corresponding increase of one response/record. We attribute this adjustment to an increase in the number of submissions we received over the last few years.

Dated: July 6, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

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